

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA

v.

GORDON FREEDMAN, et al.,

Defendants

18-CR-217 (KMW)

**REPLY MEMORANDUM IN FURTHER SUPPORT OF DR. TODD SCHLIFSTEIN'S
MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR PRE-TRIAL RELIEF**

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Defendant Dr. Todd Schlifstein (“Dr. Schlifstein”) respectfully submits this Reply Memorandum in further support of his Motion pursuant to Federal Rule of Criminal Procedure 12(b)(3)(B) to dismiss Count One (Conspiracy to Violate the Anti-Kickback Statute), Count Two (Violation of the Anti-Kickback Statute), Count Three (Conspiracy to Commit Honest Services Wire Fraud), and Count Eight (Wrongful Disclosure of Individually Identifiable Health Information) of the Indictment.

ARGUMENT

In its opposition to Dr. Schlifstein’s motion to dismiss, the Government fails to demonstrate that the allegations in the Indictment specific to Dr. Schlifstein provide the requisite factual particularity to support the charged offenses. Instead, the Government argues for a pleading standard that would fail to give doctors “fair warning” that their speaking engagements—which are a common feature of the medical and pharmaceutical communities—may expose them to criminal prosecution. As Dr. Schlifstein explained in his motion to dismiss the Indictment, all of the counts against Dr. Schlifstein should be dismissed.

Dr. Schlifstein does not attempt here to repeat his arguments in favor of dismissal, but seeks only to highlight certain fundamental flaws in the Government’s Opposition. Specifically, the Government neglects to point to any allegations that, if true, would establish the existence of a quid pro quo relationship between Dr. Schlifstein’s speaking activities and prescribing Subsys. The Government further concocts—in apparent recognition that the Indictment neglects to plead the breach of fiduciary duty required for honest services fraud in the private sector—an unsupported theory of breach based on the doctor-patient relationship, even though the Indictment does not allege that Dr. Schlifstein failed to treat his patients appropriately. The Government fails to justify its decision to withhold crucial information, particularly as to the claim that Dr. Schlifstein violated HIPAA, that is necessary to prepare for trial. And the Government falls

short of showing that the co-defendants' trials should not be severed. For these reasons, and those described in the Motion, the charges against Dr. Schlifstein should be dismissed.

I. THE INDICTMENT AGAINST DR. SCHLIFSTEIN SHOULD BE DISMISSED

A. The Indictment Fails To State A Violation Of The Anti-Kickback Statute

As Dr. Schlifstein explained, Counts 1 and 2 must be dismissed because the Indictment never identifies a violation by Dr. Schlifstein of the Anti-Kickback Statute. At no point in its lengthy opposition to the co-defendants' motions does the Government effectively counter this argument. Rather, the Government urges this Court to defer this question to the jury. This Court should decline to do so.

Where, as here, the Government's baseline theory necessarily would encompass *legal* activity, in addition to prohibited activity, an indictment must specify how such conduct crossed the line. Specifically, "a fair warning should be given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed. To make the warning fair, so far as possible the line should be clear." *United States v. Bass*, 404 U.S. 336, 348 (1971) (quoting *McBoyle v. United States*, 283 U.S. 25, 27 (1931) (Holmes, J.)); *see also United States v. Lanier*, 520 U.S. 259, 266-67 (1997) (recognizing a "fair warning requirement," under which statutes must "ma[k]e it reasonably clear at the relevant time that the defendant's conduct was criminal"); *United States v. Bodmer*, 342 F. Supp. 2d 176, 181, 189 (S.D.N.Y. 2004) (citing *Lanier*, dismissing counts in indictment). "[T]he need for fair warning is particularly acute in cases such as this one where the conduct at issue is not *malum in se*, but rather is legal in certain circumstances." *United States v. One Big Six Wheel*, 987 F.Supp. 169, 181 (E.D.N.Y. 1997).

The Indictment's only allegations supporting the charge that Dr. Schlifstein violated the Anti-Kickback Statute are that he participated in the Speaker Program regarding Subsys during the same time period he prescribed Subsys to his patients. But speaker programs are "[a] common

feature of the pharmaceutical sales industry,” *United States v. TEVA Pharm. USA, Inc.*, No. 13 CIV. 3702 (CM), 2016 WL 750720, at *3 (S.D.N.Y. Feb. 22, 2016), and the speakers in such programs are typically chosen because they have experience with the pharmaceutical—often because they prescribe it. Because participating in speaker programs is an inherently lawful activity, *see* 42 U.S.C. § 1320a–7b(b)(3)(E); 42 C.F.R. § 1001.952(d), an indictment must allege more than the fact that a defendant participated in a speaker program and wrote prescriptions in the same period. For this reason, a proper allegation of an AKS violation must include an allegation of “the existence of a quid pro quo.” *State v. MedImmune, Inc.*, 342 F. Supp. 3d 544, 553 (S.D.N.Y. Sept. 28, 2018); *see also United States v. Krikheli*, 461 F. App’x 7, 11 (2d Cir. 2012).

Neither the Indictment nor the Government’s Opposition offers evidence to support the existence of a quid pro quo. As described in Dr. Schlifstein’s Motion—and acknowledged in the Government’s Opposition—Dr. Schlifstein’s prescriptions of Subsys “did not increase substantially” once he joined the Speaker Program. Ind. ¶ 98; Mot. at 4; Opp. at 10. He had been prescribing Subsys before he first became interested in being a speaker. Ind. ¶ 96. After he began speaking, his speaker engagements and prescription levels rose and fell at different times, evincing no relationship between the two. Mot. at 4.

In defense of its baseless claim that Dr. Schlifstein increased his prescriptions to gain more speaker engagements, the Government points to *non-prescribing* activity. The Opposition cites allegations that Dr. Schlifstein attempted to get “credit” for prescriptions written by his physician assistant or for persuading others to prescribe Subsys. Ind. ¶¶ 97, 99-101; Opp. at 20. Even if true, the allegations are irrelevant. The prescribing activity of other professionals—which the

Indictment does not allege Dr. Schlifstein improperly influenced—has no bearing on whether *Dr. Schlifstein* engaged in a quid pro quo (which he did not).

The Government fails to show a quid pro quo connecting Dr. Schlifstein’s participation in the Speaker Program with his prescriptions of Subsys. Without such a connection, bare allegations that he was a speaker during the same period he prescribed the pharmaceutical are insufficient to support the charges against him. *See Bass*, 404 U.S. at 348; *Lanier*, 520 U.S. at 266-67; *One Big Six Wheel*, 987 F. Supp. at 181; *MedImmune*, 342 F.Supp.3d at 553.

In a futile attempt to excuse the deficiency of the Indictment in this regard, the Government argues that such allegations are sufficient because the jury must decide whether any connection or pattern between the prescriptions and speaking activities exists. *See, e.g.*, *Opp.* at 18-20. But, even were such deference typically warranted, it cannot apply here, because the conduct at issue is legal absent the necessary quid pro quo. As a result, and because of the additional arguments contained in Dr. Schlifstein’s Motion, the charges against him should be dismissed.

B. The Indictment Fails To Allege A Breach Of Fiduciary Duty

The Government also fails to demonstrate that the allegations in support of Count Three, which charges that Dr. Schlifstein engaged in a conspiracy to commit honest services fraud, plead the necessary breach of fiduciary duty.

The Government effectively concedes that the Indictment must plead the existence and breach of a fiduciary duty, *Opp.* 28, but still never identifies how the Indictment pleads such a breach. The Government likewise acknowledges that the Indictment nowhere alleges that Dr. Schlifstein prescribed Subsys to any patient who did not need it. *See Opp.* at 30-31. Indeed, patients who were prescribed Subsys had to follow federally required procedures to ensure they fully understood the medication. *Ind.* ¶ 16.

Instead, the Government turns the fiduciary duty inquiry on its head, arguing Dr. Schlifstein could not treat his patients in a manner “unsullied by mixed motives.” Opp. at 31. But such a standard—untethered to the conduct alleged in the Indictment—sweeps so broadly as to encompass all patients Dr. Schlifstein treated. Such logic falls far short of explaining what fiduciary duty Dr. Schlifstein allegedly breached, particularly because doctors are permitted to participate in speaker programs. *See United States v. TEVA Pharm. USA, Inc.*, No. 13 CIV. 3702 (CM), 2016 WL 750720, at *3 (S.D.N.Y. Feb. 22, 2016); 42 U.S.C. § 1320a–7b(b)(3)(E); 42 C.F.R. § 1001.952(d).

C. The Indictment Fails To Adequately Plead A Violation Of HIPAA

The Government also fails to provide any plausible argument in response to Dr. Schlifstein’s motion to dismiss Count Eight of the Indictment, which alleges that Dr. Schlifstein violated certain HIPAA regulations.

As Dr. Schlifstein demonstrated, Mot. 13-14, the Indictment fails to adequately inform Dr. Schlifstein of the accusations against him, such as whose information was disclosed, to whom, and on what date. The Government claims that it is somehow “nonsensical” to require that the Indictment identify the information Dr. Schlifstein allegedly disclosed, and when and to whom he disclosed it. Opp. at 38. But the Government’s claim that it cannot reveal whose information allegedly was disclosed ignores that the Government could have chosen to file a sealed or redacted indictment to protect any information it is concerned about. *See Fed. R. Crim. P. 49.1; United States v. Edwards*, CV 18-92, 2018 WL 3553357, at *3, n.1 (D. Mont. July 23, 2018) (explaining indictment was sealed to protect personally identifying information); *United States v. Smith*, 08-cr-00031, 2017 WL 2766099, at *8 (E.D. Ky. June 26, 2017) (discussing indictment in which “home addresses of victims” were redacted). At a minimum, even a publicly filed indictment that omits the names of the patients at issue should include the other information necessary to inform

Dr. Schlifstein of the charges and allow him to prepare a defense at trial. And the Government can claim no privacy concern (and identifies none) that would have prevented it, for instance, from disclosing the dates on which Dr. Schlifstein allegedly provided protected information to an unauthorized party, or the identity of the person who allegedly received the protected information. Without that information, the Indictment fails to meet the notice standard. *See United States v. Pirro*, 212 F.3d 86, 93-94 (2d Cir. 2000); *United States v. Berlin*, 472 F.2d 1002, 1007-08 (2d Cir. 1973).

II. THE GOVERNMENT SHOULD PROVIDE A BILL OF PARTICULARS

The Government incorrectly claims that Dr. Schlifstein is not entitled to a bill of particulars. The Government acknowledges, however, that the discovery in this case is “voluminous.” *Opp.* at 38. In doing so, the Government highlights exactly why a bill of particulars is warranted.

As courts have long recognized, “sometimes, the large volume of material disclosed is precisely what necessitates a bill of particulars.” *United States v. Bin Laden*, 92 F. Supp. 2d 225, 234 (S.D.N.Y. 2000) (citations omitted). Such is the case here, where the Government has provided millions of pages’ worth of discovery. For the reasons stated in Dr. Schlifstein’s Motion, a bill of particulars is required in this case to allow Dr. Schlifstein the ability to meaningfully prepare for trial. *See* Fed. R. Crim. P. 9(f); *United States v. Davidoff*, 845 F.2d 1151, 1154 (2d Cir. 1988); *United States v. Rajaratnam*, 09-CR-1184, 2010 WL 2788168, at *2 (S.D.N.Y. July 13, 2010). In particular, the Government should inform Dr. Schlifstein of the patients whose individually identifiable health information it alleges was “disclosed,” as well as the dates on which this disclosure allegedly took place. *See* Ind. ¶¶ 167-68. Without knowing the patient identities or dates of disclosure, Dr. Schlifstein is unable to “identify with sufficient particularity the nature of the charge pending against him” or adequately prepare for trial. *Davidoff*, 845 F.2d

at 1154 (quoting *United States v. Bortnovsky*, 820 F.2d 572, 574 (2d Cir. 1987)). As noted in Dr. Schlifstein's Motion, when he previously asked the Government to provide this information, it referred him to Paragraph 74 of the Indictment, which contains none of the necessary names or dates. To date, the Government has still failed to provide Dr. Schlifstein with that information.

None of the authority the Government cites is sufficient to obviate its obligation to inform Dr. Schlifstein of what he is being accused and allow him to prepare his defense. To do so, he needs to know whose information he is alleged to have disclosed, and when he is alleged to have disclosed it.

III. DR. SCHLIFSTEIN'S TRIAL SHOULD BE SEVERED FROM HIS CO-DEFENDANTS' TRIAL

A. The Court Should Sever Dr. Schlifstein's Trial Due To Prejudicial Joinder

Dr. Schlifstein's trial should be severed from that of his co-defendants' due to prejudicial joinder under Rule 14(a). The Government's Opposition makes clear why Dr. Schlifstein would suffer prejudice without severance, particularly if his trial is not severed from that of Dr. Goldstein. *See* Mot. at 17-18. As the Government repeatedly notes, Dr. Schlifstein shared an office with Dr. Goldstein during the period pertaining to the allegations. Opp. at 9, 58; Ind. ¶ 9. The Government does not dispute that the Indictment contains significantly more egregious allegations against Dr. Goldstein than it does against Dr. Schlifstein. For example, to support its claim that Dr. Goldstein's speaker programs were a "sham," the Indictment alleges that Dr. Goldstein smoked marijuana before some Speaker Programs he led and used cocaine with Insys employees in restaurant bathrooms at other Speaker Programs. Ind. ¶ 39(a). Dr. Goldstein is alleged to have threatened to stop prescribing Subsys unless he received more Speaker Program assignments. *Id.* ¶¶ 80-82. The Indictment claims he provided a fraudulent invoice to Insys. *Id.* ¶ 83. It accuses him of aggravated identity theft, claiming he used other individuals' identifying information to

falsely sign them in to speaker programs. *Id.* ¶¶ 159-60. No similar allegations are made against Dr. Schlifstein. Allowing the jury to hear that evidence in Dr. Schlifstein’s trial would irreparably taint its view of all the Speaker Programs, not just those in which other defendants participated. *See Zafiro v. United States*, 506 U.S. 534, 539 (1993) (“When many defendants are tried together in a complex case and they have markedly different degrees of culpability, this risk of prejudice is heightened.”). Contrary to the Government’s claim, no limiting instruction would cure the harm done to Dr. Schlifstein. *United States v. Riggi*, 541 F.3d 94, 104 (2d Cir. 2008) (recognizing that “where the prejudicial spillover was so overwhelming, [limiting instructions] cannot be presumed to be effective”); *United States v. Becker*, 502 F.3d 122, 130-31 (2d Cir. 2007) (“[W]e have found it inappropriate to presume that a district court’s limiting instructions were obeyed when such instructions required jurors to perform ‘mental acrobatics.’”).

The Government reveals in its Opposition that it intends to tie Dr. Schlifstein to the other defendants’ activities. Trying Dr. Schlifstein alongside the other defendants, particularly Dr. Goldstein, would unfairly prejudice Dr. Schlifstein and deny him a fair trial. Dr. Schlifstein’s trial should be severed from those of his co-defendants. Fed. R. Crim. P. 14.

B. The Court Should Sever Dr. Schlifstein’s Trial Due To Misjoinder

The Government claims that Dr. Schlifstein’s misjoinder argument, *see* Mot. at 17-18, is premature because the question of “whether evidence proves ‘a single or multiple other independent conspiracies is a question of fact for a properly instructed jury.’” Opp. at 58 (quoting *United States v. Sureff*, 15 F.3d 225, 229 (2d Cir. 1994)). But the Government misses a crucial step. Before that question may go to the jury, the Indictment must “sufficiently allege[] a single conspiracy.” *United States v. Ohle*, 678 F. Supp. 2d 215, 222 (S.D.N.Y. 2010) (citing *United States v. Vanwort*, 887 F.2d 375, 383 (2d Cir. 1989)). The Indictment fails to do so. As described in the Motion, the Indictment alleges no facts connecting Dr. Schlifstein to a conspiracy involving

the co-defendant doctors—at most, it alleges several separate conspiracies between Insys and each defendant. Using the classic “hub-and-spoke” metaphor, the Government fails to allege a rim connecting the spokes.

The Government relies on *United States v. Rooney* for the proposition that each member of a conspiracy need not directly conspire with or even know other members. Opp. at 56 (quoting *United States v. Rooney*, 866 F.2d 28, 32 (2d Cir. 1989)). But the court in *Rooney* was considering a conspiracy wholly different than the one alleged here. Key to the *Rooney* holding was the fact that the “scheme . . . could not have been conducted without more than one ‘contributor.’” *Rooney*, 866 F.2d at 32. There is no suggestion in this case that the alleged kickback scheme “could not have been conducted” absent one of the defendants. Indeed, the Indictment offers no reason that the alleged conspiracy would not have been conducted with only a single physician participating.

The Government also expresses concern that it would have to present the same evidence multiple times, consuming considerable resources. Opp. at 61. It exaggerates the burden. The trial against each defendant would necessarily focus on the allegations against that particular defendant. The evidence presented at Dr. Schlifstein’s trial would primarily involve the allegations of his particular speaking engagements and his particular prescribing activity. Evidence of another defendant’s actions would not be necessary to prove the allegations against any other defendant. *See Ohle*, 678 F. Supp. 2d at 226-27 (granting severance motion where multiple trials would require the government to provide some of the same evidence for “context[]” but not “prove essentially the same facts more than once”).

Because the Indictment does not allege that Dr. Schlifstein participated in a single conspiracy involving the other defendants, and the Government’s arguments fail to demonstrate otherwise, Dr. Schlifstein’s trial should be severed due to misjoinder. Fed. R. Crim. P. 8(b).

CONCLUSION

For the reasons stated above and in his Motion, Dr. Schlifstein respectfully repeats his request that this Court dismiss the four counts against him. In the alternative, Dr. Schlifstein moves for a bill of particulars, *Brady* material, a scheduling order, and severance, and he joins all co-defendants' motions not inconsistent with this motion.

Dated: New York, New York
March 20, 2019

Respectfully submitted,

/s/ Alex Spiro

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